



BILLING CODE: 3410-34-P

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

[Docket No. APHIS-2012-0033]

Stine Seed Farm, Inc.; Availability of Plant Pest Risk Assessment, Environmental Assessment, and Preliminary Decision for an Extension of a Determination of Nonregulated Status of Corn Genetically Engineered for Herbicide Tolerance

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that the Animal and Plant Health Inspection Service has prepared a preliminary decision regarding a request from Stine Seed Farm, Inc., to extend to maize line HCEM485, which has been genetically engineered to be tolerant to the herbicide glyphosate, our determination of nonregulated status of Roundup Ready® corn line GA21. We are seeking comment on whether this genetically engineered corn is likely to pose a plant pest risk. We are making available for public comment our plant pest risk assessment and draft environmental assessment for the proposed determination of nonregulated status.

DATES: We will consider all comments that we receive on or before [Insert date 30 days after date of publication in the Federal Register].

ADDRESSES: You may submit comments by either of the following methods:

- Federal eRulemaking Portal: Go to <http://www.regulations.gov/#!documentDetail;D=APHIS-2012-0033-0001>.

- Postal Mail/Commercial Delivery: Send your comment to Docket No. APHIS-2012-0033, Regulatory Analysis and Development, PPD, APHIS, Station 3A-03.8, 4700 River Road Unit 118, Riverdale, MD 20737-1238.

Supporting documents and any comments we receive on this docket may be viewed at <http://www.regulations.gov/#!docketDetail;D=APHIS-2012-0033> or in our reading room, which is located in room 1141 of the USDA South Building, 14th Street and Independence Avenue SW., Washington, DC. Normal reading room hours are 8 a.m. to 4:30 p.m., Monday through Friday, except holidays. To be sure someone is there to help you, please call (202) 799-7039 before coming.

The extension request, draft environmental assessment, and plant pest risk assessment are also available on the APHIS web site at http://www.aphis.usda.gov/brs/aphisdocs/09_06301p.pdf, http://www.aphis.usda.gov/brs/aphisdocs/09_06301p_dea.pdf, and http://www.aphis.usda.gov/brs/aphisdocs/09_06301p_dpra.pdf.

FOR FURTHER INFORMATION CONTACT: Dr. John Turner, Director, Environmental Risk Analysis Programs, Biotechnology Regulatory Services, APHIS, 4700 River Road Unit 147 Riverdale, MD 20737-1236; (301) 851-3954, email: john.t.turner@aphis.usda.gov. To obtain copies of the supporting documents, contact Ms. Cindy Eck at (301) 851-3885, email: cynthia.a.eck@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

Under the authority of the plant pest provisions of the Plant Protection Act (PPA) (7 U.S.C. 7701 et seq.), the regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which

There Is Reason to Believe Are Plant Pests," regulate, among other things, the introduction (importation, interstate movement, or release into the environment) of organisms and products altered or produced through genetic engineering that are plant pests or that there is reason to believe are plant pests. Such genetically engineered organisms (GE) and products are considered "regulated articles."

The regulations in § 340.6(a) provide that any person may submit a petition to the Animal and Plant Health Inspection Service (APHIS) seeking a determination that an article should not be regulated under 7 CFR part 340. Further, the regulations in § 340.6(e)(2) provide that a person may request that APHIS extend a determination of nonregulated status to other organisms. Such a request must include information to establish the similarity of the antecedent organism and the regulated article in question.

In a notice published in the Federal Register on December 5, 1997 (62 FR 64350-64351, Docket No. 97-052-2), APHIS announced our determination of nonregulated status of Roundup Ready® corn line GA21. APHIS has received a request for an extension of a determination of nonregulated status (APHIS Number 09-063-01p) of Roundup Ready® corn line GA21 to maize line HCEM485¹ from Stine Seed Farm, Inc., (Stine Seed) of Research Triangle Park, NC. Stine Seed seeks a determination of nonregulated status of corn designated as maize line HCEM485, which has been genetically engineered to be glyphosate tolerant. In its request, Stine Seed stated that this corn is similar to Roundup Ready® corn line GA21 and, based on the similarity to the antecedent organism, is unlikely to pose a plant pest risk and, therefore, should not be a regulated article under APHIS' regulations in 7 CFR part 340.

¹ The terms "corn" and "maize" both refer to Zea mays. In this notice, we refer to "maize line HCEM485" as this is the name used by Stine Seed in its extension request to identify its GE corn. Otherwise, we use the more common term "corn" when referring to Zea mays.

As described in the extension request, maize line HCEM485 has been genetically engineered by a 6.0 kb corn genomic fragment, originally isolated from a bacterial chromosome library derived from the corn inbred line B73, containing a modified form of the endogenous Zea mays EPSPS encoding gene. The antecedent organism, Roundup Ready® corn line GA21, was made with a 1.3kb restriction fragment of the corn EPSPS gene. Both corn lines were produced with the same mutations responsible for conferring glyphosate herbicide tolerance. Maize line HCEM485 is currently regulated under 7 CFR part 340. Interstate movements and field tests of maize line HCEM485 have been conducted under notifications acknowledged by APHIS.

Field tests conducted under APHIS oversight allowed for evaluation in a natural agricultural setting while imposing measures to minimize the risk of persistence in the environment after completion of the test. Data are gathered on multiple parameters and used by the applicant to evaluate agronomic characteristics and product performance. These and other data are used by APHIS to determine whether the new variety poses a plant pest risk.

In section 403 of the PPA, “plant pest” is defined as any living stage of any of the following that can directly or indirectly injure, cause damage to, or cause disease in any plant product: A protozoan, a nonhuman animal, a parasitic plant, a bacterium, a fungus, a virus or viroid, an infectious agent or other pathogen, or any article similar to or allied with any of the foregoing. APHIS prepared a plant pest risk assessment (PPRA) and has concluded that maize line HCEM485 is similar to the antecedent organism and is unlikely to pose a plant pest risk.

APHIS has also prepared a draft environmental assessment (EA) in which it presents two alternatives based on its analyses of data submitted by Stine Seed, a review of other scientific data, and field tests conducted under APHIS oversight. APHIS is considering the following alternatives: (1) Take no action, i.e., APHIS would not change the regulatory status of maize line

HCEM485 and it would continue to be a regulated article, or (2) make a determination of nonregulated status of maize line HCEM485.

The draft EA has been prepared to provide the APHIS decisionmaker with a review and analysis of any potential environmental impacts associated with the proposed determination of nonregulated status of maize line HCEM485. The draft EA was prepared in accordance with (1) the National Environmental Policy Act of 1969 (NEPA), as amended (42 U.S.C. 4321 et seq.); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (2) regulations of the Council on Environmental Quality for implementing the procedural provisions of NEPA (40 CFR parts 1500-1508); (3) USDA regulations implementing NEPA (7 CFR part 1b); and (4) APHIS' NEPA Implementing Procedures (7 CFR part 372).

Based on APHIS' analysis of field and laboratory data submitted by Stine Seed, references provided in the extension request, peer-reviewed publications, information analyzed in the EA, and the similarity of maize line HCEM485 to the antecedent organism, Roundup Ready® corn line GA21, APHIS has determined that maize line HCEM485 is unlikely to pose a plant pest risk. We have therefore reached a preliminary decision to approve the request to extend the determination of nonregulated status of Roundup Ready® corn line GA21 to maize line HCEM485, whereby maize line HCEM485 would no longer be subject to our regulations governing the introduction of certain genetically engineered organisms.

Paragraph (e) of § 340.6 provides that APHIS will publish a notice in the Federal Register announcing all preliminary decisions to extend determinations of nonregulated status for 30 days before the decisions become final and effective. In accordance with § 340.6(e) of the regulations, we are publishing this notice to inform the public of our preliminary decision to extend the

determination of nonregulated status of Roundup Ready® corn line GA21 to maize line HCEM485.

APHIS will accept written comments on the draft EA and PPRA regarding a determination of nonregulated status of maize line HCEM485 for a period of 30 days from the date this notice is published in the Federal Register. The draft EA and PPRA, as well as the extension request and preliminary determination for maize line HCEM485, are available for public review as indicated under ADDRESSES and FOR FURTHER INFORMATION CONTACT above. Copies of these documents may also be obtained by contacting the person listed under FOR FURTHER INFORMATION CONTACT.

After the comment period closes, APHIS will review all written comments received during the comment period and any other relevant information. All comments received regarding the EA and PPRA will be available for public review. After reviewing and evaluating the comments on the EA and PPRA, APHIS will furnish a response to the petitioner regarding our final regulatory determination. APHIS will also publish a notice in the Federal Register announcing the regulatory status of maize line HCEM485 and the availability of APHIS' written environmental decision and regulatory determination.

Authority: 7 U.S.C. 7701-7772 and 7781-7786; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.3.

Done in Washington, DC, this 22nd day of February 2013.

Michael Gregoire

Deputy Administrator, Biotechnology Regulatory Services, Animal and Plant Health Inspection Service.

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